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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,899	06/04/2004	Ryan L. Goosen	71202-0046	6956
20915 7590 03/12/2007 MCGARRY BAIR PC 171 MONROE AVENUE, N.W. SUITE 600 GRAND RAPIDS, MI 49503			EXAMINER SOLANKI, PARIKHA	
			ART UNIT	PAPER NUMBER
			3737	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/12/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/709,899

Applicant(s)

GOOSEN ET AL.

Examiner

Parikha Solanki

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/8/04, 3/8/05</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statements (IDS) submitted on 8 November 2004 and 8 March 2005 were filed after the mailing date of the application for patent on 4 June 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### *Double Patenting*

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1-54 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-54 of copending Application No. 11/275,919. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-25 and 29-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Beckman et al (US PG Pubs. No. 2005/0234336), previously cited by Applicant, hereinafter Beckman ('336).

Regarding claims 1-25 and 50-54, Beckman ('336) discloses an expandable imaging marker comprising a metal radiopaque element for x-ray imaging and a polyvinyl alcohol (PVA) element for ultrasound imaging (§ 0020, 0021, 0023, 0027, 0033). Beckman ('336) discloses that one element of the marker may be embedded in the other element (§ 0028), and the metal element may be of any asymmetric shape (Fig. 3A, § 0073). Beckman ('336) also discloses the marker for use with MRI imaging (Abstract).

Regarding claims 29-30, Beckman ('336) discloses that the marker is compressed and sized to fit within a standard biopsy needle (§ 0035, 0051).

Regarding claims 31-49, Beckman ('336) discloses all features of the marker as for claims 1-30. Beckman ('336) additionally provides a cannula, a pull wire, a stylet used for advancing the marker towards the distal end of the catheter to effect ejection of the marker through an expulsion opening, an introducer, and a squeeze handle (§ 0018).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 26-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Beckman ('336). Beckman ('336) substantially teaches all features of the present invention as applied to claims 1-25 above. Beckman ('336) fails to provide specific dimensions for the marker before and after expansion. Beckman ('336) does teach that the marker "must expand quickly to a size larger than needle tract" and that the marker "can be used in a variety of cavity sizes—large and small and can be adaptable to a specific deployment means" (§ 0051). In light of these teachings, it would therefore have been obvious to one of ordinary skill in the art at the time of invention to make the marker of Beckman ('336) of an inner diameter between 0.01 and 0.03 inches, such that the marker can fit within a standard biopsy needle during delivery, and wherein the outer diameter can expand to approximately twice the inner diameter so as to effectively fill the cavity.

### ***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Foerster et al (US PG Pubs. No. 2005/0165305), Burbank et al (US PG Pubs. No. 2002/0188196), Jones et al (US PG Pubs. No. 2004/0236212) and Barsch (US Patent No. 6,234,177) disclose related imaging markers and delivery systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

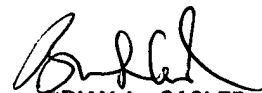
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Parikha Solanki

Examiner – Art Unit 3737



BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER